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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,883

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Jani Hamalainen

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EXAMINER

PATEL, DEVANG R

ART UNIT

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4111

MAIL DATE

DELIVERY MODE

12/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,883	Applicant(s) HAMALAINEN ET AL.	
	Examiner Devang Patel	Art Unit 4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/5/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 1** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. The phrase "outer layer not blended with such an additive" emphasis added) is indefinite because it is unclear whether this limitation requires the outer layer to free of any particulate additive, any type of additives or just free of particulate PTFE. For the purpose of examination, the claim is interpreted to have an outer layer which is not blended with a particulate PTFE. Clarification is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-3 and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontirroche et al. (US 5538510) in view of Ren (US 6086970).

b. Regarding **claim 1**, Fontirroche et al. discloses catheter plastic tubing comprising an outer plastic layer and an inner plastic layer, the materials in the inner and outer layers are different from each other (col. 2, line 1). The inner plastic layer defines a catheter lumen having the wall surface with lower frictional characteristics. Conventionally, it is known to have a catheter lumen with lubricating coating containing PTFE (col. 1, line 23) and such lumen provides desired low friction for a guide wire (col. 2, lines 4-14). The inner lumen layer with PTFE coating defines claimed "inner region." The outer plastic layer may be nylon or PET, providing a greater stiffness than the material of inner layer (col. 2, line 20). Fontirroche et al. does not teach inner region containing *particulate* additive comprising at least PTFE. However, Ren (drawn to film coated surface guide wire tubes) discloses extruded tubing having a lubricating PTFE powder, this tubing has an enhanced lubricity and collapse strength, and also providing an external lubricant comprising PTFE particles to further enhance the lubricity to reduce friction of a guide wire within a lumen of a tubing (abstract; col. 2 lines 13-48; col. 3, lines 3-7; col. 4 lines 12-40). It would have been obvious in the art to form the inner plastic tubing layer of Fontirroche using a tubing composition similar to the one suggested by Ren since it would provide an enhanced lubricity and collapse strength to a finished tubing of Fontirroche et al. While the modified tubing of Fontirroche et al is not intended for guiding a filler wire, in view that the

finished tubing of Fontirroche and Ren is indistinguishable from the claimed invention, and in view that the inner plastic tubing is used as a guide wire tube, the modified plastic tubing of Fontirroche must be capable of guiding a filler wire.

c. Regarding **claims 2 and 7**, Fontirroche et al. does not disclose the additive composition including particulate silicon (claim 2) or molybdenum sulfide (claim 7). However, Ren discloses the use of hard particles such as silica, mica, glass bead, talc, and molybdenum disulfide (synonym of molybdenum sulfide) in combination with polymers to reduce the sliding friction of the two surfaces (col. 3, lines 30-37). Silica (silicon dioxide) particles are taken to be embraced by particulate silicon, since it does not positively require the silicon to be an element as opposed to be compound. Ren further states: *"The addition of hard particles in combination with a lubricating solid, such as PTFE, improves lubricity over either compound added alone"* (col. 3, line 44).

d. Regarding **claim 3**, Fontirroche et al. does not teach additive composition of about 12-20% comprising about 12-17 wt% PTFE and about 1-3 wt% silicon. Ren discloses "PA compound 9" with lubricant composition of 3% PTFE and 5% of silica (Table 1). Absent any showing of unexpected result, the recited composition would have been obvious to one in the art making the modified plastic tubing of Fontirroche et al, because one in the art would have determined, by routine experimentation, a suitable composition in order to form resultant tubing having the desired characteristics of having an enhanced lubricity and strength.

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6. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fontirroche et al. and Ren as applied to claim 1 above, and further in view of Hermann et al. (US 5843031).

e. Neither Fontirroche et al. nor Ren teaches the thickness of additive layer being 0.2 mm - 0.5 mm. Hermann et al. discloses the tubular inner liner having thickness in the range from about 0.08 mm to 0.15 mm (col. 6, lines 25-31).

Claimed and prior art ranges do not overlap but are close such that one skilled in the art would have expected them to have the same property of providing lubrication. It would have been obvious to choose the instantly claimed range (0.2 mm-0.5 mm) for the intended purpose of guiding a filler wire through process optimization, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [MPEP 2144.05].

7. **Claims 5-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontirroche et al. and Ren as applied to claim 1 above, and further in view of Fugoso et al. (US 6179811).

f. As to **claim 5**, neither Fontirroche et al. nor Ren teaches the base material of guide tube being HDPE. Fugoso et al., drawn to a catheter comprising guide wire shaft, discloses the guide wire shaft formed out of HDPE (col. 3, line 30).

The claim would have been obvious because the substitution of HDPE taught by Fugoso et al. in the outer plastic tubing material (nylon or PET) of Fontirroche et

al. would have yielded predictable result of greater stiffness to a person of ordinary skill in the art at the time of the invention.

g. Regarding **claim 6**, neither Fontirroche et al. nor Ren teaches specified inner and outer diameter range. Fugoso et al. discloses the guide wire shaft having an inner diameter of 0.41 mm and an outer diameter of 0.58 mm. Fugoso et al. further declares: "those skilled in the art would recognize that the dimension varies depending on the application and the size of the device being passed" (col. 3, lines 30-37). Accordingly, it would have been obvious to select the inner diameter in the range of 2-4 mm and outer diameter in the range of 4-7 mm for intended use of guiding the filler wire.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jamison (Handbook of Lubrication and Tribology, 1994) discloses various tribological plastics formulated with internal lubricating additives (pg. 131). Jamison discloses Nylon 6/6 (PA) material comprising 18% PTFE and 2% silicon (Table 6) and states: "*Other additives, notably PTFE, molybdenum disulfide, and graphite powders, and silicon and mineral oils decrease friction and wear*" (pg. 134, para. 3).

Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVANG PATEL whose telephone number is (571)270-

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3636. The examiner can normally be reached on Monday thru Thursday, 8:00 am to 5:30 pm, EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on 571-272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DP

/Sam Chuan C. Yao/
Supervisory Patent Examiner, Art Unit 4111